UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

JOE FLORES, an individual, and
CONSUELO FLORES, as court-appointed conservator and guardian of JOE FLORES, as individuals and on behalf of all others similarly situated,

Plaintiffs,

Case No. 11-
Hon.

v.

UNITED STATES OF AMERICA
555 4th Street Northwest
Washington, DC 20001,

CLASS ACTION COMPLAINT

U.S. DEPARTMENT OF DEFENSE
1400 Defense Pentagon
Washington, DC 20301,

TRICARE MANAGEMENT ACTIVITY
5111 Leesburg Pike Skyline 5, Suite 810
Falls Church, Virginia 22041,

and

ROBERT M. GATES
United States Secretary of Defense
1000 Defense Pentagon, Room 3E880
Washington, DC 20301,

jointly and severally,

Defendants.

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CLASS ACTION COMPLAINT

Plaintiffs Consuelo Flores, as court-appointed conservator and guardian for Joe Flores, and Joe Flores, as individuals and on behalf of all others similarly situated, by their attorneys, Mantese Honigman Rossman and Williamson, P.C., and for their Class Action Complaint, state as follows:

I. INTRODUCTION TO THE PARTIES AND THE NATURE OF THE COMPLAINT

1. Joe Flores is a veteran of the United States Armed Services, who served our nation's Marine Corps honorably for 20 years. Joe served in Vietnam, and retired as a highly decorated Master Sergeant.

2. Since suffering a stroke in 2003, Joe Flores has been "locked in" his own body, completely paralyzed from head to toe, with absolutely no motor function other than the ability to move his eyes and eyelids.

3. Joe is a quadriplegic and suffers from "Locked-In Syndrome," a neurological disorder characterized by the complete paralysis of the voluntary muscles in all parts of the body, except for those that control eye and eyelid movement.

4. This lawsuit arises out of the Department of Defense's unlawful refusal pay for the medically and psychologically necessary health care to which Joe is entitled by federal law. Joe and Consuelo Flores, Joe's daughter, guardian and conservator, bring this lawsuit to compel the Department of Defense to pay for the skilled nursing facility care that Joe earned as a result of his 20 years of sacrifice and service to the nation and that Joe requires to fend off death and to live as healthy, humane, and decent of a life as his devastating medical condition permits.

5. While Joe possesses full cognitive function, he has no control over his body or head. His arms, legs, hands, feet, neck, head, tongue, and vocal chords are immobile.

6. Joe cannot move, chew, or swallow.

7. Joe cannot even breathe sufficiently on his own.

8. Joe's only ability to "communicate" is as follows – he blinks his eyes for "No," and he looks upward for "Yes."

9. All the while, Joe is fully conscious and aware of his surroundings. Every day, he confronts the prospect of unimaginable and claustrophobic torment for the rest of his life.

10. At all times, Joe has a tracheostomy tube running through his neck; an oxygen concentrator running through his tracheostomy; a feeding tube running through his stomach; and a supra-pubic catheter running through his abdomen into his bladder.

11. These devices, properly operated and constantly maintained by skilled personnel, along with extensive medical and skilled nursing care, keep Joe alive.

12. Meanwhile, Joe repeatedly suffers serious infections. And he is at constant risk of contracting new infections, including life-threatening, systemic infections.

13. Indeed, Joe's debilitating and perilous condition places him in constant danger of serious illness or death, and he requires constant skilled care and supervision to prevent serious illness or death.

14. Given the radical stripping away of most of the abilities and capacities that define a human life, the stark existential isolation that is Joe's lot, and the grim reality that this is a fate from which there will never be reprieve, Joe's psychological condition and emotional life are also uncertain and perilous.

15. Joe's precarious physical and psychological condition, coupled with his inability to move or talk, which renders him unable to help himself and makes it extraordinarily difficult for him to enlist the assistance of others, means that Joe teeters on the brink of serious illness and death at every moment and demands that he receive constant skilled monitoring, assessment,

care, and treatment.

16. Importantly, Joe deserves such care, because he earned it with 20 years of sacrifice and service to our nation.

17. Joe resides at the Crestmont Healthcare Center ("Crestmont"), a skilled nursing care facility in Fenton, Michigan, where he receives around-the-clock skilled nursing care and medical care supervised by a physician, all of which is medically necessary for his condition.

18. Joe has resided at Crestmont since 2004, after he was treated at a hospital and rehabilitation facility following his stroke in 2003.

19. By virtue of his service in the military, Joe Flores is entitled by federal law, 10 U.S.C. ch. 55 ("military health benefits statute"), to certain health care benefits, as are all active duty and certain retired members of our nation's armed forces.

20. With the exception of up to $1,000 for deductibles and co-pays incurred each year by active duty members and their dependents and $3,000 per year for deductibles and co-pays incurred each year by military retirees and their dependents, federal law requires the Department of Defense to pay for all medically necessary and appropriate health care of military beneficiaries without limit. 10 U.S.C. 1079(b)(5), 1086(b)(4)).

21. The Secretary of Defense and his designees in the Department of Defense, who administer the military's managed health care program ("TRICARE"), have unlawfully refused to provide certain of those health care benefits to Joe Flores.

22. Specifically, the health benefits to which Joe Flores is entitled pursuant to federal law, and which Defendants are denying to Joe Flores, include, *inter alia*, "[s]killed nursing facility care . . . [that] shall continue to be provided as long as medically necessary and appropriate." 10 U.S.C. 1074j(b).

23. For several years, all of Joe's medical care, skilled nursing care, and all expenses

in any way related to Joe's condition were paid by TRICARE.

24. However, after providing coverage for Joe Flores's skilled nursing care at Crestmont for 5 years, and despite Joe's obvious medically perilous condition, Defendants have now abruptly halted TRICARE coverage for Joe's care.

25. In the blink of an eye, in February 2010, Defendants cut off and refused to provide skilled nursing coverage for Joe's care.

26. According to Defendants, the extremely nuanced, life-saving, and around-the-clock medical care provided to Joe Flores by Crestmont is merely "custodial care" that is not "medically necessary," and is, therefore, not covered under the military health benefits statute.

27. According to Defendants' latest determination, the care provided to Joe Flores by Crestmont is not "skilled nursing care" and is not "medically necessary and appropriate."

28. Since Defendants' denial of skilled nursing coverage to Joe in February 2010, whereby TRICARE refused to pay for the care Joe received from November through December, 2009, TRICARE has continued to refuse to pay for Joe's skilled nursing care.

29. By cutting off funding for Joe's care, Defendants have condemned Joe to an even worse fate than his tragic medical condition imposes.

30. By refusing to cover the skilled nursing care which he requires, the Department of Defense is imposing a death sentence on Joe, a highly decorated Master Sergeant who served and sacrificed for our nation for 20 years.

31. Since Defendants' denial of coverage for Joe's skilled nursing care, Joe has been paying for his care at Crestmont – which totals approximately $7,000 per month – out of his own extremely limited personal funds.

32. Very soon, Joe will deplete his savings, will be unable to pay for his care, and will face immediate and irreparable harm, including, potentially, death.

33. As explained thoroughly herein, the care that Joe receives at Crestmont is "skilled nursing" care, "medically necessary and appropriate" health care, and not "custodial care," under the military health benefits statute and its accompanying regulations.

34. To suggest that Joe requires anything less than continuous, skilled nursing care provided by medical professionals, educated and trained in the proper treatment, assessment, and support techniques required by individuals with Joe's medical condition, is both absurd and disingenuous.

35. The care Joe needs simply to survive is intensive and nuanced. Every minute of the day, Joe relies upon skilled care to keep him alive, including, *inter alia*, skilled care to assess and prevent systemic infection and to maintain proper breathing.

36. The skilled care provided to Joe at Crestmont is not merely to sustain a certain quality of life and to mitigate his physical and mental suffering, but rather it is to sustain life itself.

37. Defendants' determination that the care Joe receives at Crestmont is "custodial care" and not "skilled nursing care" is contrary to law, regulation, and congressional intent.

38. Defendants lack substantial evidence for their denial of skilled care coverage to Joe, and their denial is arbitrary and capricious.

39. While the cost of providing skilled nursing care is significant, federal law does not permit Defendants to deny payment for medical care because of its substantial cost.

40. Congress has decided, as provided by 10 U.S.C. ch. 55, that military beneficiaries, active duty and retired, deserve the highest level of medical care; it is the least our country can do for those who risk everything.

41. Joe Flores, who honorably served this country for 20 years, deserves better from our federal government.

42. The injustice and the absurdity, the inhumanity and the illegality of the Department of Defense's refusal to pay for medically necessary, skilled nursing care for a man who sacrificed for his country and who now teeters precariously on the edge of the final abyss, is indefensible.

43. By semantic artifice, procedural trick, and their overwhelming resource advantage versus an overwhelmed veteran lacking sufficient resources, the Department of Defense is flouting the declared instruction of Congress to "create and maintain high morale by . . . providing an improved program of medical and dental care," 10 U.S.C. 1071, and to provide "all health care to which a covered beneficiary is entitled," 10 U.S.C. 1099.

II. JURISDICTION AND VENUE

44. This action arises out of, *inter alia*, Defendants' violation of the military health benefits statute, 10 U.S.C. ch. 55, and Defendants' final agency action denying health care coverage to Joe Flores.

45. The Administrative Procedure Act ("APA") provides for judicial review of final agency action, 5 U.S.C. 701, et seq.

46. The Court has subject matter jurisdiction under 28 U.S.C. 1331.

47. Venue is appropriate in the Eastern District of Michigan under 28 U.S.C. 1391(e).

III. THE PARTIES

A. PLAINTIFFS

48. Plaintiff Consuelo Flores is the 27-year-old daughter and court-appointed conservator and guardian of Joe Flores.

49. Consuelo Flores visits her father at the Crestmont facility in Fenton, Michigan virtually every day, despite working full-time at a job in Troy, Michigan.

50. Joe Flores's only other child is a son who is honorably serving in the United

States Marine Corps, like his father, and is currently fighting for our country overseas in Afghanistan.

51. Plaintiff Joe Flores, the TRICARE beneficiary at the heart of this case, a 20-year veteran of the United States Armed Services, was born on April 2, 1950. He is 61 years old.

52. Joe Flores resides at Crestmont HealthCare Center, 111 Trealout Drive, Fenton, Michigan 48430.

53. Consuelo Flores and Joe Flores bring this case on behalf of themselves and all similarly-situated active duty and retired members of the United States Armed Services and their dependents, entitled by law to receive health care benefits pursuant to 10 U.S.C. ch. 55.

B. DEFENDANTS

54. TRICARE Management Activity ("TMA"), located at 5111 Leesburg Pike, Skyline 5, Suite 810, Falls Church, Virginia 22041-3205, is responsible for managing the Department of Defense's TRICARE health care system for active duty and retired uniformed service members and their families.

55. The United States Department of Defense, located at 1400 Defense Pentagon, Washington, DC 20301-1400, is an agency of the United States government. TMA manages the TRICARE health care program under the authority of the Assistant Secretary of Defense for Health Affairs.

56. Robert M. Gates currently serves as the United States Secretary of Defense, and is located at 1000 Defense Pentagon, Room 3E880, Washington, DC 20301-1000. The Secretary of Defense has delegated authority to the Assistant Secretary of Defense for Health Affairs to provide policy guidance, management control, and coordination as required for all Department of Defense health and medical resources and functional areas, including health benefit programs. Nonetheless, Secretary Gates maintains ultimate authority, direction and control over the

Department of Defense, including the TRICARE health benefits program.

IV. THE ADMINISTRATIVE PROCESS HAS NOT PROVIDED RELIEF

A. OVERVIEW OF THE TRICARE ADMINISTRATIVE PROCESS

57. Defendants have authorized Managed Care Support Contractors ("MCSC") to make the initial determination of benefits in response to requests for coverage of and payment for health care services under TRICARE. The MCSC is required to issue a dated initial determination in the form of an Explanation of Benefits ("EOB") or a letter. The initial determination must contain sufficient information to enable the beneficiary to understand the basis for the denial. The initial determination must state with specificity what services and supplies are being denied and for what reason. See 32 C.F.R. 199.10; TRICARE Operations Manual 6010.56-M, ch. 12, sec. 1.

58. If the initial determination results in a denial of coverage or other adverse decision, the TRICARE beneficiary has 90 days from the initial determination to file a request for reconsideration. See 32 C.F.R. 199.10; TRICARE Operations Manual 6010.56-M, ch. 12, sec. 1.

59. If a request for reconsideration is not filed, the initial determination is final and subject to judicial review pursuant to the APA, 5 U.S.C. 704.

60. If a request for reconsideration is filed, the MCSC will either reverse the initial determination denying health care benefits and issue an EOB, or the MCSC will issue a letter explaining why the initial denial is upheld.

61. If the reconsideration results in a denial of health care coverage or other adverse decision, the TRICARE beneficiary has 60 days from the date of the reconsideration decision to request a formal review or a hearing with TMA.

62. If an appeal is not filed within 60 days of the date of the reconsideration decision,

the determination is final and subject to judicial review pursuant to the APA, 5 U.S.C. 704.

B. TRICARE'S RECENT DENIAL OF COVERAGE TO JOE FLORES

63. In this case, the MCSC issued an initial denial notice/letter to Crestmont on February 4, 2010, denying skilled nursing coverage to Joe Flores for November through December, 2009.

64. On February 19, 2010, Crestmont sent a signed letter to TRICARE requesting reconsideration of the MCSC's initial determination, stating that Crestmont "is formally appealing your November claim for Mr. Flores. He ***does*** require skilled nursing care and not custodial. His condition has not changed since being admitted in 2004."

65. On March 16, 2010, TRICARE issued a reconsideration determination in which TRICARE affirmed the initial denial of skilled nursing coverage to Joe Flores.

66. As indicated in its March 16, 2010 reconsideration determination, TRICARE reviewed some of Joe Flores's medical records and summarily concluded that "[t]he skilled nursing facility (SNF) stay [is] denied as not medically necessary." According to TRICARE, "[t]he care was custodial and not covered, except for any drugs and supplies."

67. In the March 16, 2010 reconsideration determination, TRICARE acknowledged the following facts regarding Joe's medical condition, treatment, and previous coverage of his health care by TRICARE:

a. "Our Medical Advisor ***previously*** reviewed the SNF stay for June 21, 2006 - April 20, 2009 and determined that this patient's care was medically necessary and covered per TRICARE policy and the Code of Federal Regulations."

b. "The diagnoses are septicemia, pseudomonas infection, urinary tract infections, and stroke. He was hospitalized March 4, 2006 - March 9, 2006 and July 30, 2008 - August 1, 2008."

c. "This patient has several chronic medical diseases[.]"

d. "His medications are via his PEG [feeding tube.]"

e. "He has locked in syndrome and is total care."

f. "He has a J tube and trach[eostomy]."

g. He has occupational therapy and physical therapy.

h. He "has pressure ulcers . . . with wound care."

68. Despite acknowledging the foregoing, and with utter, complete, and shocking disregard of Joe Flores's overall medical and psychological condition, extreme propensity for infection, and all of the skilled care, assessment, and supervision attendant to his precarious medical situation, TRICARE mindlessly concluded that, "[u]nfortunately, the tube feedings alone do not require 24/7 SNF care or SNC [skilled nursing care]. There is no medical complexity of care that requires 24/7 SNF care."

69. TRICARE then attempted to justify its drastic shift in position regarding coverage for Joe's care – having ***covered*** Joe's skilled nursing care for several years prior – by baldly claiming that "[p]rior review periods have been approved based on the feeding tube alone, but this on its own is not criteria for skilled level need. . . . The administration of and caring for tube feedings does not require the services of a registered nurse at this level of care."

70. TRICARE concluded in its March 16, 2010 reconsideration determination that Joe's care provided by Crestmont was "custodial by TRICARE definition" and "shall remain denied as not medically necessary and not covered per TRICARE Policy and the Code of Federal Regulations."

71. On May 20, 2010, Consuelo Flores and Joe Flores filed an appeal of TRICARE's March 16, 2010 reconsideration determination that denied SNF coverage to Joe.

72. By letter on June 3, 2010, TRICARE rejected the appeal, which was a final agency decision.

73. Defendants' denial of coverage to Joe Flores under TRICARE is final. Any

further appeal would be futile and cause irreparable harm to Joe who, in the very near future, will not be able to afford his medically necessary health care without payment from Defendants. The skilled nursing facility where Joe resides will likely deny care to Joe soon if Defendants continue to refuse to pay for his care.

C. TRICARE'S SHIFTING POSITIONS REGARDING COVERAGE TO JOE FLORES

74. Perhaps most striking about the administrative saga concerning Joe Flores's skilled nursing coverage is TRICARE's alarming and radical shifting and flip-flopping of its position regarding its coverage of Joe's care at Crestmont.

75. First, from the moment Joe was admitted to Crestmont in 2004, until 2009, TRICARE covered all of Joe's care at Crestmont.

76. Then, in 2009, TRICARE abruptly stopped paying for Joe's care at Crestmont, claiming, out of nowhere, that Joe's care was "custodial" in nature (effective beginning with the period August 1, 2008 through April 30, 2009).

77. Consuelo Flores and Joe Flores filed an appeal of TRICARE's 2009 denial, and, according to TRICARE's decision, Joe's "case along with the . . . TRICARE Policies and all currently available information was . . . sent for professional review to determine if the care provided was medically necessary/appropriate and provided at the appropriate level of care."

78. On September 21, 2009, after conducting such a review, TRICARE promptly issued a reconsideration determination, finding as follows:

> In summary, the nursing home services received by Joe Flores performed from June 21, 2006 through April 30, 2009 ***were not custodial by TRICARE definitions and can be covered per the TRICARE contractual language***.

79. In its 2009 reconsideration determination, TRICARE recognized, *inter alia*, the following points, not unlike those recognized in its 2010 decision discussed above:

a. "The Medical Advisor has reviewed the medical records pertaining to Joe Flores

for long term care at Crestmont HCC for the dates of service June 21, 2006 through April 30, 2009."

b. "He has several chronic medical diseases[.]"

c. "His medications are via his PEG [feeding tube.]"

d. "He has locked in syndrome and is total care."

e. "He has a J tube and tracheotomy."

f. "He receives occupational therapy[.]"

g. "His PEG-tube feedings are the only source of his nutrition."

80. In its 2009 reconsideration determination, TRICARE stated that "[t]he following conclusion can be drawn from the medical records . . . : Joe Flores was not receiving custodial care according to the Code of Federal Regulations[.]" TRICARE then recited its regulatory definition of "custodial care," as found in 32 C.F.R. 199.2(b).

81. TRICARE also stated, in its 2009 reconsideration determination, that, "similarly, he [Joe Flores] was not receiving custodial care, according to the TRICARE Reimbursement Manual[.]" TRICARE then recited its published policy regarding its coverage of "skilled nursing services" which "must be skilled services."

82. Then, just 5 months after issuing this 2009 reconsideration determination unequivocally stating that Joe's care at Crestmont is skilled nursing facility care that TRICARE must pay for under the military health benefits statute, TRICARE abruptly stopped paying for Joe's care in February 2010 (with such denial effective November 2009, forward).

83. TRICARE's February 2010 decision, which led to the filing of this lawsuit, represents a stunning, totally inexplicable, and completely unjustified 180-degree shift in TRICARE's position regarding Joe Flores's medical coverage.

84. The inconsistencies and drastic shifts in TRICARE's positions regarding coverage

for Joe's care at Crestmont is alarming, and renders TRICARE's position undeserving of judicial deference.

85. Joe Flores's medical condition has not changed since he was admitted to Crestmont in 2004, as Crestmont stated in its February 19, 2010 signed letter to TRICARE.

86. Joe's condition has not improved one iota. Indeed, he has only deteriorated with time, all of which is corroborated by his long-time treating physician at Crestmont.

87. At a minimum, Defendants' shifting and inconsistent positions trigger a very "hard look" review by this Court.

88. Indeed, Defendants' shifting and inconsistent positions, with no significant change in factual circumstances, gives rise to an inference that Defendants' most recent decision is arbitrary and capricious.

V. OVERVIEW OF LOCKED-IN SYNDROME

89. Locked-In Syndrome, also known as cerebromedullospinal disconnectionis, is a rare neurological disorder that typically results from a pontine hemorrhage or infarct, and which disrupts and damages the lower portions of the brain.

90. Locked-In Syndrome is caused by damage to the pons, a part of the brainstem that contains nerve fibers that relay information to other areas of the brain.

91. Locked-In Syndrome results in the complete paralysis of voluntary muscles in all parts of the body except for those that control eye movement. Those afflicted are alert and fully conscious, but cannot move. Only movements of the eyes and blinking are possible.

92. Locked-In Syndrome results in anarthria, the total loss of the motor ability to speak.

93. Locked-In Syndrome is also called pseudo-coma, because affected individuals are conscious, but make little body movement – like unconscious patients.

94. While damage to the lower portions of the brain affects muscle control, it does not affect a Locked-In Syndrome patient's ability to think, to reason, and to feel emotional and physical pain and other sensations.

95. Locked-In Syndrome patients remain aware and conscious of their surroundings and their cognitive ability, including their ability to experience emotions, is unaffected.

96. There is no cure for Locked-In Syndrome.

VI. JOE FLORES'S MEDICAL CONDITION, DEVICES, AND CARE

A. INTRODUCTION

97. In September 2003, while living alone, Joe Flores suffered a spontaneous stroke that severely damaged the lower, pons portion of his brain.

98. When he suffered the stroke, Joe fell to floor, and he remained on the floor for two days, until a friend found him.

99. During the time he laid on the floor, post-stroke, Joe sustained damage to his muscles, tissue, and kidneys, which were failing at the time his friend discovered him.

100. After he was found, an emergency helicopter airlifted Joe to a hospital because his condition was so dire.

101. At the hospital, Joe underwent various treatments, was placed on a ventilator because he could not breathe on his own, and had a tracheostomy tube surgically placed into a hole in the front of his neck.

102. After staying in the hospital for a couple of weeks, Joe was eventually weaned off of the ventilator, but the tracheostomy was left in, because Joe was still not able to breathe sufficiently on his own and required – and still requires – around-the-clock, supplemental, humidified oxygen pumped into his lungs.

103. In 2004, after his stay in the hospital, Joe was transferred to a rehabilitation

facility in Missouri, where he remained for several months.

104. Thereafter, Joe was transferred to Crestmont to receive medical and skilled nursing care for his permanent, perilous medical condition.

105. When Joe was admitted to Crestmont on April 3, 2004, the admission sheet states that Joe's diagnoses included, *inter alia*, Locked-In Syndrome, septicemia (bacteria in the blood, often associated with severe infections), bronchitis, and pneumonia.

106. Several other ***skilled*** nursing facilities were unwilling to accept Joe because of his medical condition and the dangers it presents, including his permanent, open tracheostomy.

107. The other skilled nursing facilities would not accept Joe, at least in part, because they believed that their staff was not sufficiently skilled to care for Joe.

108. Joe's guardian was, therefore, fortunate to find Crestmont, which was willing to accept Joe and provide skilled care for his perilous medical condition.

B. OVERVIEW OF JOE'S CONDITION AND CARE

109. Joe relies on around-the-clock skilled nursing care, including skilled active treatment, skilled assessment, and skilled supervision, to stay alive, to prevent further deterioration of his health, and to live as healthy, humane, and decent a life as his devastating medical condition permits.

110. To achieve these goals, a medically skilled professional must actively treat, assess, and/or supervise nearly every aspect of Joe's care and every aspect of his condition.

111. Without the care of medically skilled professionals, Joe's breathing would weaken, his food intake and urine output would decrease, his muscles would deteriorate, and he would suffer from innumerable, systemic diseases and infections, as his body is extraordinarily susceptible to illness due to his significantly weakened immune system.

112. Without the care of medically skilled professionals, Joe's health would quickly

deteriorate. He would likely die within minutes, days, or weeks.

113. As a military veteran, Joe is used to sacrifice, and somehow he is able to find the internal strength to push through his anguish each day and go on. Joe cannot go on, however, without skilled nursing care at a skilled nursing facility.

114. Dr. Amy Daros, a specialist in geriatric medicine, has been Joe's treating physician since Joe arrived at Crestmont in April 2004.

115. Dr. Daros sees and/or treats Joe constantly, on an as-needed basis, which often means seeing him every week or two, depending on Joe's current condition.

116. According to Dr. Daros, Joe's condition has not improved since he was admitted to Crestmont. Indeed, his condition has worsened in some respects.

117. Given her intimate experience with Joe's individual condition over many years, as well as her vast medical knowledge about quadriplegia and other illnesses and injuries, Dr. Daros has a strong opinion as to whether Joe requires medically skilled care in a skilled nursing facility.

118. In Dr. Daros's medical opinion, Joe Flores belongs in a skilled nursing facility receiving skilled nursing care.

119. According to Dr. Daros, given Joe's precarious medical condition, it is impossible for Joe to receive sufficient care at home, without skilled medical assistance.

120. According to Dr. Daros, if Joe were not in a skilled nursing facility, he would deteriorate, and almost certainly deteriorate quickly.

121. According to Dr. Daros, skilled nursing professionals at Crestmont perform nearly every single aspect of Joe's care:

a. Nurses prepare and administer Joe's medications.

b. Nurses prepare, administer, and maintain Joe's tube feedings.

c. Nurses perform all periodic and routine assessments of Joe, including monitoring

his symptoms and indications of infection and other illness.

d. Nurses prepare, administer, and maintain Joe's catheter.

e. Nurses prepare, administer, and maintain Joe's tracheostomy.

f. Nurses prepare, administer, and maintain Joe's breathing tube and oxygen concentrator.

g. Nurses prepare and administer Joe's aerosol breathing treatments.

h. Nurses supervise and assist with re-positioning Joe.

122. Unskilled aides' participation in Joe's care is limited to cleaning Joe, washing his bedding, and assisting with re-positioning him (under the supervision of a nurse).

C. JOE'S TRACHEOSTOMY

123. Joe has a permanent tracheostomy, a surgically created hole, through the front of his neck.

124. Through the tracheostomy is a plastic tube placed directly into Joe's windpipe, which is held tight by a band around his neck.

125. Joe's tracheostomy tube provides long-term ventilation and air passage, because Joe cannot breathe sufficiently or cough effectively to clear secretions in his throat.

126. Joe's tracheostomy tube also allows additional, humidified oxygen to be pumped into his windpipe through a separate tube, as described below.

127. Several very serious complications can arise due to Joe's tracheostomy.

128. According to Dr. Daros, Joe's long-time treating physician, if Joe's tracheostomy becomes plugged with mucous, fluid, or other secretions, which come up regularly and often drain through Joe's tracheostomy, this can immediately affect Joe's ability to breathe and he may suffocate in a short amount of time.

129. Further, according to Dr. Daros, if the tracheostomy tube becomes dislodged or

comes out accidentally, this could immediately affect Joe's ability to breathe and he may suffocate.

130. According to Dr. Daros, re-installing (and/or removing) the tracheostomy tube into Joe's trachea, given his condition, involves medical skill.

131. According to Dr. Daros, if an unskilled individual does not properly and skillfully install Joe's tracheostomy, he will not be able to breathe properly and he may suffocate.

132. Of significant importance to Joe's care, according to Dr. Daros, is the fact that Joe cannot talk or move. If Joe starts to feel that his tracheostomy is blocked, coming out, or not installed properly, or that his breathing is decreasing, Joe is helpless – he cannot alert someone nor can he do anything himself to remedy the problem.

133. According to Dr. Daros, Joe can gradually experience difficulty and decreased breathing due to a blockage or other problem with his tracheostomy, which can turn deadly in a matter of minutes, depending on whether he is being assessed properly and consistently.

134. According to Dr. Daros, given his tracheostomy, Locked-In Syndrome, and his overall condition, Joe must have consistent, medically skilled monitoring of his breathing.

135. Indeed, according to Dr. Daros, the only reason why Joe has not suffered more serious complications related to his tracheostomy is ***because*** of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

136. Furthermore, according to Dr. Daros, Joe is at risk for infection at the site of his tracheostomy, and in his trachea and lungs.

137. Many infection-related and other complications often arise from the long-term presence of a permanent tracheostomy, as in Joe's case.

138. Joe is at particularly high-risk for these complications, because he is also immuno-compromised.

139. Without proper care and cleaning, Joe may suffer complications from the tube, including bleeding and infection.

140. Joe's windpipe itself may become damaged for a number of reasons, including pressure from the tube, bacteria that cause infections and form scar tissue, or friction from a tube that moves too much.

141. Joe may experience thinning (erosion) of the trachea from the tube rubbing against it.

142. Joe may experience the narrowing or collapse of the airway above the site of the tracheostomy.

143. Given Joe's overall condition, he requires skilled care for all aspects of his tracheostomy, as well as regular examination of his airway by a skilled medical professional.

144. Thus far, Joe has only been able to avoid certain complications related to his tracheostomy because of the around-the-clock skilled nursing care Joe receives at Crestmont.

D. JOE'S OXYGEN CONCENTRATOR

145. Joe cannot, breathing on his own, deliver sufficient oxygen throughout his body.

146. Joe requires the assistance of an oxygen concentrator, a machine that continuously delivers supplemental, humidified oxygen into Joe's lungs and makes it easier for his body to absorb the oxygen it needs.

147. On one end, the oxygen concentrator is plugged into an electrical outlet and, on the other end, a tube runs from the oxygen concentrator to a mask, which fits over Joe's tracheostomy

148. According to Dr. Daros, Joe's nurses humidify the oxygen before it passes to Joe's lungs, by inserting sterile water into the concentrator, allowing the oxygen to flow through the water on its way to Joe's lungs.

149. According to Dr. Daros, Joe's oxygen concentrator currently delivers about 2 supplemental liters of oxygen per minute to Joe's lungs.

150. According to Dr. Daros, if Joe was not getting this 2 liters of supplemental oxygen per minute, he would get sick – fast. He would struggle to breathe, and he would deteriorate very quickly.

151. Indeed, according to Dr. Daros, there have been instances when storms have caused Crestmont to lose power, and by the time a back-up power source was in place, Joe's breathing had become significantly labored.

152. A skilled professional is required to properly maintain and use the oxygen concentrator in Joe's case.

153. The reason why Joe has been able, thus far, to avoid more serious complications related to his oxygen intake is because of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

E. JOE'S BREATHING TREATMENTS

154. According to Dr. Daros, Joe also requires approximately 3 aerosol breathing treatments per day, which are performed by Joe's nurses. He has always required these treatments, which nurses administer to him routinely.

155. According to Dr. Daros, Joe's breathing treatments are performed by hooking up a machine, which aerosolizes the oxygen, to the tube that comes from Joe's oxygen concentrator, so that the medicine passes through Joe's oxygen mask at the same time as the oxygen that is pumped in from the concentrator.

156. The medicine causes Joe's airways to relax and dilate, making it easier for air and secretions to pass through them, and the medicine decreases irritation in the lungs.

157. According to Dr. Daros, when Joe's respiratory problems flare up, he requires the

breathing treatments more often. When he was sick with tracheal bronchitis in February 2011, for instance, he required the breathing treatments about every 4 to 6 hours, around-the-clock.

158. A skilled professional is required to assess the need for, manner, duration, and frequency of Joe's breathing treatments.

F. JOE'S FEEDING TUBE

159. Because Joe is unable to open and close his mouth or swallow, he must be fed entirely through a percutaneous endoscopic gastrostomy ("PEG"), which is a feeding tube that is surgically placed through Joe's abdominal wall and into Joe's stomach.

160. According to Dr. Daros, Joe is prone to contracting an infection at the site where his feeding tube penetrates his skin, and the dressing and skin area must be closely monitored.

161. According to Dr. Daros, Joe's feeding tube may accidentally come out – for example, when re-positioning Joe – which may result in bleeding and other complications.

162. According to Dr. Daros, in such a circumstance, Joe's feeding tube must be quickly replaced.

163. According to Dr. Daros, if Joe's feeding tube comes out or becomes loose and needs to be re-inserted, a skilled medical professional must put the tube back in exactly the medically right way, and evaluate and assess Joe's overall status as well as the accuracy of the tube placement.

164. Because Joe's feeding tube is permanently used for his feedings, the tube requires periodic replacement because the tube material deteriorates over time.

165. Indeed, according to Dr. Daros, the only reason why Joe has not suffered more serious complications related to his feeding tube is ***because*** of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

166. Other potential complications can arise from the permanent feeding tube inserted

into Joe's stomach.

167. A typical complication is moderate gastric leakage. Gastric juices are highly corrosive and may cause skin irritation.

168. The lower, internal portion of the feeding tube may migrate back into the stomach, which may lead to kinking, luminal occlusion of the tube, reflux, and/or aspiration.

169. Because aspiration can still occur with a feeding tube in place, Joe's head must be kept above the level of the tube to prevent aspiration.

170. Aspiration is the entry of secretions or foreign material into the trachea and lungs. If enough material were to enter Joe's lungs, he could simply drown. Also, even small volumes of gastric acid contents could fatally damage Joe's lung tissue.

171. Research reveals that persons with feeding tubes are at high risk for pneumonia, fever, infection, and sepsis, all of which can be deadly and are frequently caused by bacteria/germs associated with a feeding tube and its improper handling.

172. Joe is particularly vulnerable to such illnesses and infections, because he is significantly immuno-compromised.

173. Given Joe's overall condition, he requires skilled care for all aspects of the care related to his feeding tube, including ensuring that the tube is regularly and properly checked, cleaned, dressed, not causing infection, unblocked, and secured.

174. The only reason why Joe has not suffered worse complications related to his feeding tube is because of the skilled nursing care he receives at Crestmont.

G. JOE'S SUPRA-PUBIC CATHETER

175. Because Joe is unable to move or voluntarily urinate or defecate, his waste is discharged primarily through a supra-pubic catheter, which is surgically placed directly into Joe's bladder through a hole in his abdomen, just above his pubic bone.

176. Urine drains into an external collection device, which is strapped to Joe.

177. According to Dr. Daros, initially Joe had a Foley catheter, which goes directly into the penis. However, with Joe's history of prostate enlargement, bladder problems, and complications from his stroke, he became unable to urinate that way during 2006/2007. He, therefore, required a supra-pubic catheter to be surgically placed into his bladder through his abdomen.

178. According to Dr. Daros, if Joe's supra-pubic catheter becomes blocked or comes out accidentally, not only will it be painful for Joe, but medical skill would be required to replace the catheter.

179. According to Dr. Daros, as a matter of course, skilled nurses at Crestmont replace Joe's catheter at least every 30 days.

180. According to Dr. Daros, one of the biggest problems that can arise at any moment from Joe's supra-pubic catheter is a partial blockage that may go undetected.

181. Sediments, clots, encrustations, or the abdominal wall itself can block the supra-pubic catheter.

182. According to Dr. Daros, a person who is not medically skilled may not realize, or even be able to adequately assess and recognize, a partial blockage simply by analyzing Joe's urine output.

183. According to Dr. Daros, if a partial or total blockage occurs, Joe would get fluid overloaded, with fluid backing up throughout his body. Fluid would eventually back up into his lungs. This would cause severe breathing problems for Joe, leading to heart failure and death. Also, Joe's bladder would start descending, which can cause problems with his bowels as well.

184. The only reason why Joe has not suffered more serious complications related to his supra-pubic catheter is ***because*** of the around-the-clock skilled nursing care, assessment,

supervision, and rapid intervention that Joe receives at Crestmont.

185. Indeed, according to Dr. Daros, on at least two occasions when Joe's supra-pubic catheter was not draining well, skilled nurses at Crestmont recognized the problem in time and it was resolved accordingly. Without skilled nursing care, the problem likely would not have been recognized and would have had dire consequences.

186. According to Dr. Daros, a blockage in the catheter can be a dangerous, more insidious problem, although it is less obvious than, for example, the catheter coming out.

187. Furthermore, the catheter insertion site in Joe's abdomen and the tube must be properly cleansed daily and covered with dry gauze.

188. According to Dr. Daros, Joe has a substantial risk for infection at the catheter site, given that his skin is broken and a tube is going into his body.

189. Complications arising from a supra-pubic catheter include urinary tract and blood infections (both of which Joe has contracted), kidney infections, skin breakdown, bladder stones, and blood in the urine.

190. The only reason why Joe has not suffered even worse complications related to his supra-pubic catheter is because of the skilled nursing care he receives at Crestmont.

H. JOE'S CHRONIC INFECTIONS AND AILMENTS

191. Given Joe's precarious overall medical condition, and his suppressed immune system, Joe is extremely prone to, and constantly suffers from various infections and ailments.

192. According to Dr. Daros, Joe's total lack of mobility contributes to his suppressed immune system, because moving around is highly beneficial for a human's immune system, and Joe cannot move at all.

193. Making matters worse, according to Dr. Daros, Joe suffers from reduced kidney function (chronic renal disease), which is getting worse and which requires constant monitoring.

194. Skilled care is required, according to Dr. Daros, to ensure that Joe is kept properly hydrated, without over-hydrating him, and that nothing is done that might damage his kidneys further.

195. Also, according to Dr. Daros, Joe's entire system is constantly assaulted by organisms coming in through his entry sites – at his tracheostomy, feeding tube, and catheter – and Joe constantly has to fight off those harmful organisms.

196. According to Dr. Daros, Joe is constantly at risk for infection because of his overall condition and the fact that his skin is broken at his tracheostomy, feeding tube, and catheter entry sites, where foreign tubes travel through unnatural, incision holes in his body.

197. Indeed, according to Dr. Daros, around the beginning of his stay at Crestmont, Joe had to be admitted to the hospital multiple times when he was stricken with pneumonia because his trachoeostomy tube was not functioning properly. For Joe, the danger of contracting and suffering from respiratory infection is increased because his lungs are in a weakened state.

198. At any of his three entry sites, according to Dr. Daros, Joe can easily contract an infection that grows slowly and can easily go unnoticed by a medically unskilled person.

199. According to Dr. Daros, Joe could easily become very sick with an infection that could develop insidiously, initially with only slight changes in vital signs – e.g., blood pressure, body temperature – that only a medically skilled professional will recognize.

200. According to Dr. Daros, given Joe's Locked-In Syndrome and other health problems, an infection that starts at a localized site can soon become a systemic infection that travels throughout his bloodstream and that, if it goes unnoticed, may cause Joe to go into septic shock.

201. Joe has contracted many infections due to his perilous medical condition, even while receiving skilled nursing care. According to Dr. Daros, the only reason why Joe has not

suffered even worse infection, or death, is ***because*** of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

202. According to Dr. Daros, it is difficult even for a medically skilled professional to communicate effectively with Joe in order to fully understand his symptoms and ailments.

203. According to Dr. Daros, if Joe was cared for in shifts of unskilled persons, it would be extremely difficult for them to discern clues to the status of his health, given his lack of communication ability.

204. Also, according to Dr. Daros, Joe is under constant, significant physical and emotional stress that also contributes to his systemic vulnerability, because – due to his "locked-in" condition – he always has to wait for a medical professional to ask him just the right series of questions in order for he or she to even begin to understand Joe's symptoms or ailments.

205. According to Dr. Daros, Joe's condition results in Dr. Daros having to see Joe at least every month because of some problem, warning sign, or infection Joe is experiencing.

206. According to Dr. Daros, approximately every 1 - 2 months, Joe contracts an infection of some kind.

207. According to Dr. Daros, most recently, around March 2011, Joe had an infection in his testicles. Previously, Joe had a separate infection in his testicles for which he had to be admitted to the hospital for medical treatment.

208. According to Dr. Daros, the infections in Joe's testicles may arise because of, *inter alia*, his supra-pubic catheter, which causes Joe to be prone to infection in that region.

209. According to Dr. Daros, this most recent infection in his testicles was a typical example in which medically skilled, nuanced, and lengthy "communication" with Joe was necessary to pinpoint the infection. Dr. Daros and Joe – with Joe only blinking his eyes – had to review body-part-by-body-part until Dr. Daros began to understand Joe's problem.

210. In performing their around-the-clock assessments of Joe's condition, the skilled nursing professionals at Crestmont must engage in such nuanced "communication," including asking a series of skilled questions, in order to properly assess Joe's condition on an hourly basis.

211. Also recently, according to Dr. Daros, in January and February, 2011, Joe had a combination of tracheal bronchitis, a bowel ailment, and possibly viral gastroenteritis. Dr. Daros had to visit Joe multiple times to attend to his illnesses.

212. According to Dr. Daros, Joe has had multiple infections, including, *inter alia*, numerous painful urinary tract infections over the years, bladder infections, eye infections, tracheal bronchitis, and infections in his lungs.

213. According to Dr. Daros, Joe is prone to frequent eye infections, and even had an eye infection a couple of years ago that progressed so rapidly that the doctor transferred Joe to a hospital emergency room.

214. According to Dr. Daros, with skilled medical assessment and quick intervention, resulting in antibiotics being given to Joe without delay, his infections and illnesses have been treated and kept under control.

215. Without the around-the-clock presence of skilled medical assessment and rapid intervention at Crestmont, Joe would probably have died many times.

216. According to Dr. Daros, even the administration of Joe's medications requires careful attention and skill. If his medications are not crushed properly, and pushed through his feeding tube properly, his tube may become blocked.

217. Also, according to Dr. Daros, Joe must sometimes receive medications intravenously, most often associated with one of his infections, when antibiotics cannot be provided through Joe's feeding tube.

218. Furthermore, as acknowledged by TRICARE in its March 16, 2010

reconsideration determination (denying skilled nursing coverage to Joe), Joe's chronic infections and conditions include a diagnosis of septicemia, which is the presence of bacteria in the blood and is often associated with severe infections.

219. Septicemia is a serious, life-threatening condition that gets worse very quickly. It can arise from infections throughout the body, including infections in the lungs, abdomen, and urinary tract. It may arise before or at the same time as infections of the bone, central nervous system, heart, or other tissues.

220. Septicemia can begin with fevers, chills, breathing difficulties, and/or increased heart rate, and the symptoms rapidly progress to shock with fever or decreased body temperature, falling blood pressure, confusion and other changes in mental status, and blood clotting problems.

221. Also acknowledged by TRICARE in its March 16, 2010 reconsideration determination (denying skilled nursing coverage to Joe), Joe's chronic infections and conditions include a diagnosis of pseudomonas infections, potentially fatal bacteria that affect patients with immune-deficiency.

222. Pseudomonas infections can develop in many locations, including the skin, subcutaneous tissue, bone, ears, eyes, urinary tract, and heart valves. The site varies with the portal of entry and the patient's particular vulnerability.

223. Pseudomonas is a common cause of urinary tract infections and usually is seen in patients like Joe who have had urologic manipulation. A pseudomonas pulmonary infection can occur in patients like Joe with a tracheostomy.

224. Further, as acknowledged by TRICARE itself in its March 16, 2010 reconsideration determination (denying skilled nursing coverage to Joe), Joe's chronic infections and conditions include a diagnosis of urinary tract infections.

225. Joe is highly prone to urinary tract infections, because of an enlarged prostate and the supra-pubic catheter placed directly into his bladder.

226. Because bacteria on the catheter can infect the bladder, care must be taken to keep the catheter clean and properly in place.

227. A urinary tract infection for someone in Joe's condition can reach the kidneys, triggering a cascading series of further problems. Being able to detect this, given Joe's Locked-In Syndrome and other health problems, would be very difficult or impossible for an unskilled person, as the signs include fever, pain in the back or side, and nausea, all of which are not easily assessed or recognized in someone with Joe's medical problems and extremely limited communication ability.

228. If one of Joe's recurring urinary tract infections reaches his kidneys – and Joe's kidneys are already diseased and operating with significantly lowered function – and the infection goes untreated, it could cause Joe's kidneys to fail, resulting in Joe's death.

229. Further, Joe has a permanent diagnosis of methicillin-resistant staphylococcus aureus (or "MRSA"), an infection caused by a strain of staph bacteria that has become resistant to the antibiotics commonly used to treat ordinary staph infections.

230. Most MRSA infections occur in people like Joe, who have been in hospitals or other health care settings. MRSA infections like Joe's are often associated with invasive procedures and devices.

231. Joe always carries the MRSA infection. His infection moves between inactivity and flare-ups.

232. Because Joe's MRSA infection can resist the effects of common antibiotics, it can be very difficult to treat when it flares up.

233. Serious complications can result when Joe's MRSA infection flares up, as the

infection can spread and become life-threatening.

234. A flare-up in Joe's MRSA infection can quickly affect his bloodstream, lungs, heart, bones, and joints.

235. The medical knowledge and training needed to recognize, assess, monitor, and to actively, remedially, and prophylactically treat all of Joe's various infections, illnesses, diseases, and ailments, especially given Joe's Locked-In Syndrome and other health problems, can only be provided by skilled medical professionals.

236. The only reason why Joe has not suffered even worse infection or even more serious complications, including death, from the infections he has contracted, is because of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

I. JOE'S PRESSURE ULCERS

237. Joe has suffered from pressure ulcers, which are areas of Joe's skin that break down after he has stayed in a position for too long without properly shifting weight.

238. The constant pressure against his skin reduces blood supply to that area, and the affected tissue dies. A pressure ulcer starts as reddened skin that gets worse over time.

239. Joe is very prone to pressure ulcers, given that he is completely immobile, bedridden, older, has a chronic condition that prevents proper blood flow, has fragile skin, and has urinary and bowel incontinence.

240. Joe has developed several pressure ulcers, and the only reason why these ulcers have not caused more damage to Joe is because of the skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont.

241. Pressure ulcers eventually develop into craters that damage the tissue below the skin, and they can become so deep that they cause damage to the muscle and bone, and even the

tendons and joints.

242. Proper care of pressure ulcers is very important to prevent infection, which Joe is also very susceptible to contracting.

243. Joe requires a skilled professional to assess whether his pressure ulcers show signs of infection, given Joe's precarious medical condition, and given that an infection from a pressure ulcer could easily spread throughout Joe's body.

244. Joe requires regular re-positioning into appropriate positions in order to avoid the occurrence of pressure ulcers, and Joe requires medical treatment when ulcers develop.

245. According to Dr. Daros, if Joe is not re-positioned at least every 1 - 2 hours, and if he is not re-positioned properly, his skin will break down.

246. According to Dr. Daros, if his re-positioning is not performed in a medically proper manner, given Joe's medical condition, the re-positioning itself can cause pressure wounds to Joe's skin. This has happened already to Joe's feet, even when receiving skilled care.

247. According to Dr. Daros, Joe's re-positioning must be performed by at least 2 people, and at Crestmont, a skilled nursing professional either assists with the re-positioning or oversees the re-positioning to ensure it is performed properly.

248. The only reason why Joe has not sustained worse pressure wounds, more often, is because of the skilled nursing care and medical supervision he receives at Crestmont.

J. JOE'S OCCUPATIONAL AND PHYSICAL THERAPY

249. Joe receives both occupational and physical therapy at Crestmont, according to Dr. Daros.

250. Skilled professionals at Crestmont perform range of motion therapy with Joe, moving his arms and legs around in order to prevent deterioration of his muscles.

251. Also, skilled professionals at Crestmont perform therapy to prevent the

development of limb contractures, which occur when muscles or tendons have been in a tightened state for a prolonged period of time, causing them to become permanently clenched, and painful.

252. Once limb contractures develop, they can only be repaired through orthopedic surgery.

253. Skilled professionals at Crestmont put splints on Joe's hands for hours at a time throughout the day to prevent Joe's muscles and tendons from getting too stiff, and they also place boots on his feet to prevent foot drop which can be caused by Joe being bedridden.

K. JOE'S NEED FOR CONSTANT, SKILLED ASSESSMENT AND MONITORING

254. As explained above, Joe is extremely prone to and almost constantly is contracting infections and other illnesses.

255. Indeed, Joe's medical history shows, and his long-time treating physician strongly confirms, that Joe is – at nearly every second – on the cusp of contracting an infection, disease, or serious illness in addition to his constant, grave underlying illnesses, diseases, and deficits which are themselves always vulnerable to deterioration.

256. Given Joe's long, deep, and varied history of infections, combined with, among other things, his highly suppressed immune system, his various medical devices and open entry sites, his kidney disease, his breathing problems, and his precarious overall medical condition, bedridden and permanently "locked-in" his body, and his inability to communicate other than moving his eyes, at nearly every moment of his life Joe is literally in a life-or-death situation that requires consistent, skilled care, skilled assessment, and skilled monitoring.

257. Joe's skilled nursing care is continual, ongoing, and never stops, because during every moment in Joe's life, literally, there exists great risk for an emergency situation that can turn serious, or deadly, within a very short period of time.

258. The fact that Joe cannot move or speak, and that he can only move his eyes, in light of his already perilous medical condition, renders him in great need of skilled nursing care.

259. Joe cannot provide reports of his symptoms or conditions, like other patients.

260. Joe requires a highly skilled questioner and assessor, around-the-clock, to question and assess his condition, symptoms, and warning signs, as if he or she were putting together pieces of a puzzle or trying to anticipate or predict the future.

261. A medically skilled professional must be consistently, anticipatorily, and holistically assessing Joe's global condition, and staying on top of his changing symptoms and ailments at all times, in order to catch and diagnose issues early, so that they do not quickly develop into a medical issue that kills Joe.

262. An unskilled person alone without skilled assistance and supervision cannot adequately perform this life-saving role.

263. According to Dr. Daros, Joe needs 24/7 skilled monitoring of his condition.

264. According to Dr. Daros, of vital importance to keeping Joe healthy is continuity in monitoring Joe, constant monitoring of Joe, diagnosing sickness in Joe quickly, and rapid intervening to prevent Joe from deteriorating quickly.

265. According to Dr. Daros, it is the constant, skilled monitoring of Joe's condition that has allowed Crestmont to diagnose Joe's problems early and to medically intervene before Joe deteriorates beyond the point of no return.

266. According to Dr. Daros, the only reason why Joe has not suffered more serious problems over the last 6 years is precisely ***because*** he has received skilled nursing care at Crestmont. That is precisely why his infections and other ailments have stayed, relatively speaking, under control.

267. According to Dr. Daros, the skilled nurses at Crestmont check on Joe

approximately every hour, 24 hours a day, 7 days a week, to assess his condition. Skilled nurses – not unskilled aides – perform this all-important function.

268. According to Dr. Daros, the skilled nurses at Crestmont use all of their skill to "communicate" with Joe about his condition, and doing so is not easy, even for the skilled nurses. While Joe can feel pain, discomfort, and any other sensation, Joe of course has no ability to alert someone to these facts or affirmatively indicate his problems.

269. According to Dr. Daros, given that Joe can only move his eyes and eyelids, Joe's questioners have to be so knowledgeable that they are able to ask just the right questions, in the right order, going bit-by-bit through his physical and mental state, and body-part-by-body-part, through every imaginable nuanced issue that could be causing problems to Joe.

270. According to Dr. Daros, the questioner even has to routinely flip-flop his or her questions, asking questions that require differing responses from Joe's eye movements, in order to make sure that Joe is following the questioner.

271. According to Dr. Daros, the skilled nursing assessments of Joe that are performed at Crestmont approximately every hour, 24 hours a day, 7 days a week, prevent Joe from deteriorating quickly.

272. According to Dr. Daros, approximately every hour, 24 hours a day, a skilled nursing professional also must check Joe's airway to make sure it is clear.

273. According to Dr. Daros, given Joe's overall condition, without constant skilled assessment, Joe will likely deteriorate from a problem within a very short period of time.

274. According to Dr. Daros, although Joe has no ability to move, he sometimes spontaneously coughs so strongly that it makes him slump to the side. Once Joe is slumped to the side, he, of course, cannot move his face or neck or return to his original position.

275. According to Dr. Daros, she has found Joe lying bent over on his side, with his

head against his bedrail, due to one of these spontaneous coughs.

276. According to Dr. Daros, one of Joe's spontaneous coughs and resulting slump over can easily cause Joe's tracheostomy tube to become dislodged or obstructed, causing an immediate, life-or-death emergency. Alternatively, or in addition, it can cause Joe's face to become stuck in any loose bedding or items that could block his airway.

277. According to Dr. Daros, Joe's spontaneous coughs have caused him to pitch forward and even to fall out of his bed altogether. One such instance, around 2004, caused Joe to fall out of bed and hit his head, causing a contusion on his head. Other times, Joe has received cuts and bruises from pitching forward after a cough and hitting his head on the bedrail or dresser.

278. Joe is constantly in a medically perilous condition, with ailments attacking and challenging his body from all directions often at the same time, and Joe requires skilled nursing care to help minimize the possibility of catastrophic harm.

L. JOE'S MENTAL HEALTH RENDERS ASSESSMENT EVEN MORE DIFFICULT

279. Understandably, given the unbearably claustrophobic and horrifically isolated existence that Joe – fully consciously – permanently labors under, Joe has experienced mental health problems since being "locked-in" his own body.

280. As explained by Dr. Daros, Joe is mentally like us, except he cannot move, and he does not have personal interactions, and this has negatively affected his mental and emotional state.

281. According to Dr. Daros, Joe has a diagnosis of depression, which was reached while Joe was at Crestmont, around 2006.

282. According to Dr. Daros, Joe is currently on antidepressant medication which he has been taking since around 2007.

283. According to Dr. Daros, Joe's mental condition would deteriorate if he was not taking the antidepressant medication.

284. Before taking this antidepressant medication, according to Dr. Daros, Joe had wanted to end his life. Around 2007 – after having previously wanting all life support measures taken if necessary to save his life – Joe moved to "hospice" status.

285. According to Dr. Daros, hospice status meant that Joe would not have any blood draws and he would not be hospitalized, resuscitated, or revived (if he went into septic shock).

286. Eventually, according to Dr. Daros, Joe came off of hospice status and started receiving new antidepressant medication which has helped, but his mental condition remains uncertain.

287. According to Dr. Daros, Joe has days when he will not attempt to "communicate" with anyone because, understandably, he just wants to be left alone.

288. According to Dr. Daros, it is never entirely clear whether Joe is working with you when he does "communicate" with his eyes. A skilled professional has to know exactly what to be aware of when engaging in such "communication," including understanding Joe's depression to recognize what may be meaningful communication and what may not be.

289. Furthermore, according to Dr. Daros, given his massive stroke, Joe has a risk of dementia and further vascular problems with his brain, which may affect his mental condition, and make whatever "communication" ability Joe possesses even less effective.

290. Finally, according to Dr. Daros, Joe has been diagnosed with a facial recognition problem, which prevents him from consistently recognizing who is talking to him. He may recognize voices, but he confuses faces. This problem further complicates whatever "communication" ability Joe possesses, and makes it even less effective. A skilled professional must monitor this condition and assess how it may be affecting Joe's ability to "interact" at all.

291. Joe has already been sentenced to a life of isolation and despair.

292. For Defendants to now deny Joe TRICARE coverage for his medically necessary, skilled nursing care, which is required to keep Joe alive day-to-day and which is required to manage the various infections and illnesses which are constantly threatening his life, is not only inhumane, but it is a clear violation of federal law.

VII. JOE FLORES IS ENTITLED, BY FEDERAL LAW, TO TRICARE COVERAGE FOR THE CARE HE RECEIVES AT CRESTMONT

A. OVERVIEW AND PURPOSE OF TRICARE HEALTH CARE COVERAGE

293. Congress created the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) in 1966 to improve the health care program for members of the uniformed services, retirees, and their dependents.

294. Congress expressly stated that its legislative "purpose" in enacting CHAMPUS was "to create and maintain high morale in the uniformed services by providing an improved program of medical . . . care for members and certain former members of those services, and for their dependents." 10 U.S.C. 1071.

295. Today, the CHAMPUS program is implemented through a managed health care program known as TRICARE, and is a key component to maintaining the quality of life for the men and women of the armed forces who put their lives at risk to serve this country every day.

296. According to the TRICARE regulations, subject to all applicable definitions, conditions, limitations, and exclusions, TRICARE pays for all "medically necessary services and supplies required in the diagnosis and treatment of illness or injury[.]" 32 C.F.R. 199.4(a)(1)(i).

297. TRICARE covers all care that is "medically or psychologically necessary," which the TRICARE regulations define as "[t]he frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified

professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury[.]" 32 C.F.R. 199.2(b).

298. Meanwhile, the TRICARE regulations define "appropriate medical care" as, *inter alia*, "services performed in connection with the diagnosis or treatment of disease or injury, pregnancy, mental disorder, or well baby care which are in keeping with the generally accepted norms for medical practice in the United States." 32 C.F.R. 199.2(b).

299. Further, the TRICARE regulations define the term "medical" as that "which pertains to the diagnosis and treatment of illness, injury, pregnancy, and mental disorders by trained and licensed or certified health professionals[.]" 32 C.F.R. 199.2(b).

300. The life-saving care that Joe Flores receives at Crestmont is "medically or psychologically necessary."

301. The life-saving care that Joe Flores receives at Crestmont is "appropriate medical care."

302. The life-saving care that Joe Flores receives at Crestmont is "medical."

303. Meanwhile, the military health benefits statute (10 U.S.C. ch. 55) and regulations promulgated thereunder should be construed to effectuate the purposes of the military health benefits statute – which, as Congress expressly stated, was to create an improved, not reduced, level of health care available to the men and women who serve our country's armed forces.

B. TRICARE'S BASIS FOR DENYING COVERAGE TO JOE FLORES

304. The care Joe Flores receives at Crestmont is "medically or psychologically necessary," "appropriate medical care," and "medical," and is otherwise expressly covered by the military health benefits statute as "skilled nursing facility services," as described below.

305. Despite the foregoing, TRICARE has now denied coverage for the care that Joe receives at Crestmont.

306. TRICARE has "concluded" that Joe's "SNF [skilled nursing facility] stay" at Crestmont is merely "custodial" care and, therefore, is not "medically necessary and not covered per TRICARE Policy and the Code of Federal Regulations."

C. THE CARE JOE FLORES RECEIVES AT CRESTMONT IS SKILLED NURSING FACILITY CARE WHICH FEDERAL LAW REQUIRES TRICARE TO PAY FOR

307. In the National Defense Authorization Act of Fiscal Year 2002, Public Law 107-107 (2001), Congress permanently amended the military health benefits statute (10 U.S.C. ch. 55) by adding a new statutory section entitled "Sub-acute care program." 107 P.L. 107 (2001).

308. Specifically, Congress enacted section 1074j of the military health benefits statute, which provides, *inter alia*, as follows:

> (a) Establishment. The Secretary of Defense shall establish an ***effective***, efficient, and integrated sub-acute care benefits program under this chapter . . . .
>
> (b) Benefits.
> (1) The ***program shall include a uniform skilled nursing facility benefit that shall be provided in the manner and under the conditions described in section 1861 (h) and (i) of the Social Security Act*** (42 U.S.C. 1395x (h) and (i)), except that the limitation on the number of days of coverage under section 1812 (a) and (b) of such Act (42 U.S.C. 1395d (a) and (b)) shall not be applicable under the program. Skilled nursing facility care for each spell of illness ***shall continue to be provided for as long as medically necessary and appropriate***.

10 U.S.C. 1074j (emphasis added).

309. Thus, Congress has mandated that TRICARE must provide a "skilled nursing facility benefit" to its beneficiaries, which must be provided in the identical manner and under the identical conditions as Medicare's skilled nursing benefit (sections 1861(h)-(i) of the Social Security Act).

310. As stated by Congress, the only difference between the skilled nursing benefit provided under TRICARE and that provided under Medicare shall be that, under TRICARE, the skilled nursing benefit must continue as long as the beneficiary requires the care.

311. After Congress amended the military health benefits statute by mandating the "skilled nursing facility benefit," the Department of Defense promulgated a Final Rule interpreting the legislative change and adjusting its agency regulations accordingly.

312. In its Final Rule, published at 61368 Federal Register, vol. 70, no. 204 (Oct. 24, 2005), the Department of Defense unambiguously recognized, *inter alia*, the following:

a. Congress has imposed "requirements that TRICARE establish an integrated subacute care program consisting of skilled nursing facility and home health care services ***modeled after the Medicare program***[.]"

b. "The Department believes that incorporation of actual regulatory language, in addition to applicable cross references to Medicare statutes and regulations, will only tend to ***strengthen the uniformity*** between the programs."

c. "We also believe that the Medicare cross references (i.e., the statutory and regulatory provisions) cited in the interim final rule are sufficient to maintain uniformity in benefit structure and reimbursement between the programs (i.e., ***consistency in benefit coverage*** and reimbursement between the Medicare and TRICARE programs). The cross referenced regulatory provisions implement key sections of the Social Security Act relating to covered services[.]"

d. ***The objective*** of the SNF benefit change and the revised SNF payment system is to ***make TRICARE's SNF benefit consistent with Medicare***, ***which satisfies a Congressional goal***. A ***second objective is to increase the quality of care by requiring a more detailed review of SNF cases and more appropriate placement of SNF patients***."

e. "Consistent with the statute, SNF coverage for each spell of illness shall continue to be provided for as long as medically necessary and appropriate."

313. Based on Congress's 2001 amendment to the military health benefits statute that mandated the "skilled nursing facility benefit," the Department of Defense adjusted its agency regulations accordingly.

314. TRICARE's regulations, after the legislative amendment and its Final Rule, now provide as follows, at 32 C.F.R. 199.4(b)(3)(xiv), under the heading "Covered services and supplies by special medical treatment institutions or facilities, other than hospitals or RT":

Skilled nursing facility (SNF) services. ***Covered services in SNFs are the same***

> ***as provided under Medicare*** under section 1861(h) and (i) of the Social Security Act (42 U.S.C. 1395x(h) and (i)) and 42 CFR part 409, subparts C and D, except that the Medicare limitation on the number of days of coverage under section 1812(a) and (b) of the Social Security Act (42 U.S.C. 1395d(a) and (b)) and 42 CFR 409.61(b) shall not be applicable under TRICARE. Skilled nursing facility care for each spell of illness shall continue to be provided for as long as necessary and appropriate.

315. As explained in TRICARE's Reimbursement Manual 6010.58-M, ch. 8, add. G (Feb. 1, 2008): "with one exception, the legislation [the National Defense Authorization Act of Fiscal Year 2002] revised the TRICARE SNF benefit so that it is identical to the Medicare SNF benefit[.]" "The skilled services must meet the Medicare coverage rules . . . . The one exception is that, unlike Medicare, the TRICARE benefit for a spell of illness will be unlimited."

316. Thus, the Department of Defense has expressly, repeatedly, and officially recognized that Congress required that coverage of skilled nursing facility care under TRICARE must be the same as under Medicare.

317. Further, the Department of Defense has expressly and officially recognized that the SNF benefit under TRICARE is intended to ***increase the quality of care*** for, and ***more appropriately place***, SNF patients – like Joe Flores – and that such care shall be provided under TRICARE for as long as the patient requires such care.

318. In addition to recognizing that SNF coverage under TRICARE must be the same as Medicare, the TRICARE regulations (32 C.F.R. 199.4(b)(3)(xiv)) provide a list of covered SNF services, and this list of items and services is taken wholesale from the Medicare statutory definition of SNF services (section 1861(h) of the Social Security Act, at 42 U.S.C. 1395x(h)):

> Extended care services furnished to an inpatient of a SNF by such SNF ... include:
>
> (A) Nursing care provided by or under the supervision of a registered professional nurse;
>
> (B) Bed and board in connection with the furnishing of such nursing care;

> (C) Physical or occupational therapy or speech-language pathology services furnished by the SNF or by others under arrangements with them by the facility;
>
> (D) Medical social services;
>
> (E) Such drugs, biological, supplies, appliances, and equipment, furnished for use in the SNF, as are ordinarily furnished for the care and treatment of inpatients;
>
> (F) Medical services provided by an intern or resident-in-training of a hospital with which the facility has such an agreement in effect; and
>
> (G) Such other services necessary to the health of the patients as are generally provided by SNFs, or by others under arrangements with them made by the facility.

32 C.F.R. 199.4(b)(3)(xiv).

319. The care Joe Flores receives at Crestmont clearly fits within the list of covered SNF items and services contained in the TRICARE regulations and Medicare statute. 32 C.F.R. 199.4(b)(3)(xiv); 42 U.S.C. 1395x(h).

320. Of further import, TRICARE has published on its website an "example" of SNF care that includes several skilled nursing services that Joe receives at Crestmont:

> Examples of skilled nursing care: A licensed nurse administers numerous intravenous injections, sets up and adjusts tube feeding, monitors a ventilator for an unstable condition, and changes sterile dressings on a wound, while wearing protective dress.

TRICARE News Archive, available at http://www.tricare4u.com/apps-portal/tricareapps-app/static/beneficiaries/tricare/archive.htm, last visited Apr. 29, 2011.

321. Also, separate from its list of covered SNF services, the TRICARE regulations (32 C.F.R. 199.4(b)(3)) list – as covered services/supplies in special medical treatment institutions or facilities – the following:

a. "Room and board. Includes special diets, laundry services, and other general housekeeping support services (inpatient only)."

b. "General staff nursing services."

c. "Drugs and medicines."

d. "Durable medical equipment, medical supplies, and dressings."

e. "Diagnostic services."

f. "Physical therapy."

g. "Oxygen. Includes equipment for its administration."

h. "Other medical services . . . related directly to the diagnosis or definitive set of symptoms and rendered by a member of the institution's medical or professional staff[.]"

322. The care that Joe Flores receives at Crestmont clearly fits within this list of TRICARE-covered services/supplies as well.

323. Meanwhile, TRICARE does not dispute that Crestmont and Joe Flores satisfy the TRICARE technical requirements (adopted from Medicare) for SNF coverage.

324. Crestmont is a skilled nursing facility, in accordance with 32 CFR 199.6(b)(4)(vi) and TRICARE Reimbursement Manual 6010.58-M, ch. 8, sec. 2 (Feb. 1, 2008), because it is engaged in providing to inpatients medically necessary skilled nursing care, it has a requirement that the medical care of each patient must be under the supervision of a physician, and it is providing 24-hour skilled nursing service.

325. Crestmont is authorized by TRICARE to provide skilled nursing care to TRICARE beneficiaries.

326. Joe Flores meets the technical SNF admission requirements, in accordance with 32 C.F.R. 199.4(b)(3)(xiv), and TRICARE does not claim otherwise. TRICARE acknowledges in its March 16, 2010 reconsideration determination that Joe's "qualifying [3-day] hospital stay was March 4, 2006 - March 9, 2006." Further, there is no dispute whether Joe's skilled services are related to a medical condition that was either treated during the qualifying 3-day hospital stay

or started while he was already receiving skilled nursing care.

327. As explained above, Congress has required in the clearest and most express terms possible, and the Department of Defense has repeatedly and officially acknowledged, that the coverage of SNF services under TRICARE shall be the same as under Medicare. The TRICARE skilled nursing facility benefit, passed into law by Congress in 2001, is to be the same as under Medicare, except only that TRICARE must provide the benefit to patients as long as it is medically necessary.

328. Therefore, the ***Medicare*** statute, and the skilled nursing facility (SNF) benefit regulations and policies promulgated thereunder, provide the substantive standards and guidelines under which this case must be decided.

329. Congress was well-aware of the coverage standards and guidelines for the SNF benefit under Medicare's statute, regulations, and policies when Congress mandated that SNF coverage under TRICARE would be the same as SNF coverage under Medicare.

330. Because TRICARE coverage for skilled nursing care is the same as under Medicare, if Joe Flores's care at Crestmont is skilled nursing care covered under Medicare, then his care must be covered by TRICARE.

331. The Medicare regulations, 42 C.F.R. 409.30 et seq., provide detailed, substantive guidance regarding the care, and the type of care situations, that are covered by the SNF benefit.

332. With reference to these regulations, it is indisputable that the care Joe Flores receives at Crestmont falls within the SNF benefit under Medicare standards and, thus, his care must be covered by TRICARE.

333. Importantly, Medicare regulation, 42 C.F.R. 409.32, entitled "***Criteria for skilled services and the need for skilled services***," provides as follows:

> (a) To be considered a skilled service, the service must be so inherently complex

> that it can be safely and effectively performed only by, ***or under the supervision of***, professional or technical personnel.
>
> (b) ***A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled*** (such as those listed in §409.33(d) [***custodial care***]) ***may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel***. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, ***skilled personnel may be needed to adjust*** traction ***or watch for complications***. . . .
>
> (c) ***The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed***. Even if full recovery or medical improvement is not possible, a ***patient may need skilled services to prevent further deterioration or preserve current capabilities***. For example, a terminal cancer patient may need some of the skilled services described in §409.33.

334. First, the care Joe Flores receives at Crestmont, as described thoroughly above, is performed by skilled nursing professionals and, at a minimum, must be performed "under the supervision" of such a professional.

335. Second, even if Joe Flores had a "condition that does not ordinarily require skilled services" (which he does not), Joe Flores requires skilled services "because of special medical complications," including the various devices, illnesses, and ailments related to his Locked-In Syndrome and other health problems, as described thoroughly above.

336. According to 42 C.F.R. 409.32, under these circumstances, even services that are "usually nonskilled," such as custodial care, "may be considered skilled because [they] must be performed or supervised by skilled nursing . . . personnel."

337. The Medicare Benefit Policy Manual, Chapter 8 provides even further guidance regarding the "criteria for skilled services and the need for skilled services."

338. TRICARE's own Reimbursement Manual 6010.58-M, ch. 8, sec. 2 (Feb. 1, 2008) points to this chapter of the Medicare Manual, instructing that "[c]overed SNF services must meet the requirements . . . are to be skilled services as provided in the Medicare Benefit Policy

Manual, Chapter 8."

339. Regarding the requirement that covered skilled care must be performed "under the supervision" of a skilled nursing professional, Chapter 8 of the Medicare Benefit Policy Manual explains as follows:

> "General supervision" requires initial direction and periodic inspection of the actual activity. However, the supervisor need not always be physically present or on the premises when the assistant is performing services.

340. Regarding the fact that even services that are "usually nonskilled" may nevertheless be considered skilled nursing care, because of "special medical complications" and the appropriateness of skilled supervision, the Medicare Benefit Policy Manual, Chapter 8 provides further guidance:

> In determining whether services rendered in a SNF constitute covered care, it is necessary to determine . . . whether, ***in light of <u>the patient's total condition,</u> skilled management of the services provided is needed even though many or all of the specific services were unskilled***.
>
> **EXAMPLE:**
>
> An 81-year-old woman who is aphasic and confused, suffers from hemiplegia, congestive heart failure, and atrial fibrillation, has suffered a cerebrovascular accident, is incontinent, has a Stage 1 decubitus ulcer, ***and is unable to communicate and make her needs known***. ***Even though no specific service provided is skilled, the patient's condition requires daily skilled nursing involvement to manage a plan for the total care needed, to observe the patient's progress, and to evaluate the need for changes in the treatment plan***.

341. To the extent that any of the individual services that Joe receives at Crestmont would be not "skilled care" if provided to a normal patient, all of the services are deemed "skilled care" in Joe's case because of Joe's "total condition," including, *inter alia*, Joe's Locked-In Syndrome, quadriplegia, and inability to move any part of his body or to communicate, or "make his needs known" other than by moving his eyes; Joe's inability to independently breathe on his own; Joe's long and varied history of serious infections; Joe's

highly suppressed immune system; Joe's permanent tracheostomy, breathing tube, oxygen concentrator, permanent PEG feeding tube, and permanent supra-pubic catheter; Joe's various open entry sites penetrating his skin; Joe's kidney disease; Joe's depression and uncertain mental condition; and Joe's overall perilous medical condition.

342. Under these circumstances, at the ***very*** least, Joe requires skilled care "to adjust" treatment, "watch for complications," "to prevent [Joe's] further deterioration or preserve current capabilities," "to observe the patient's progress," "to evaluate the need for changes in the treatment plan," and "to manage a plan for the total care needed."

343. Furthermore, Medicare regulation, 42 C.F.R. 409.33, entitled "Examples of skilled nursing and rehabilitation services," provides that the "overall management and evaluation of care plan" constitutes skilled nursing care, as follows:

> The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, ***because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs***, promote recovery, ***and ensure medical safety***. Those activities include the management of a plan involving a variety of personal care services [custodial services] only when, ***in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel***.
>
> *Example.* An aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and ***observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing, mobility***. ***Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other***. ***Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety***. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. ***Skilled planning and management activities are not always specifically identified in the patient's clinical record***. ***Therefore, <u>if the patient's overall condition supports a finding that recovery and safety can be ensured</u>***

> ***only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided***.

344. The Medicare Benefit Policy Manual, Chapter 8 provides an additional example of when the "overall management and evaluation of care plan" constitutes skilled nursing care:

> An aged patient is recovering from pneumonia, is lethargic, is disoriented, has residual chest congestion, ***is confined to bed as a result of his debilitated condition***, and requires restraints at times. To decrease the chest congestion, the physician has prescribed ***frequent changes in position***, coughing, and deep breathing. ***While the residual chest congestion alone would not represent a high risk factor, the patient's immobility and confusion represent complicating factors which, when coupled with the chest congestion, could create high probability of a relapse***. ***In this situation, skilled overseeing of the nonskilled services would be reasonable and necessary,*** pending the elimination of the chest congestion, ***to assure the patient's medical safety***.

345. As explained thoroughly above, Joe's Locked-In Syndrome and various other serious health problems – his "overall condition" – absolutely "supports a finding that . . . safety can be ensured only if" his "total care is planned, managed, and evaluated," even including "skilled overseeing of the nonskilled services," by professional personnel. Therefore, "it is appropriate to infer that skilled services are being provided" to Joe.

346. In addition, Medicare regulation, 42 C.F.R. 409.33, entitled "Examples of skilled nursing and rehabilitation services," provides that the "observation and assessment of the patient's changing condition" constitutes skilled nursing care, as follows:

> Observation and assessment constitute skilled services when the skills of a technical or professional person are required ***to identify and evaluate the patient's need for modification of treatment or for additional medical procedures*** until his or her condition is stabilized.
>
> *Examples.* A patient with congestive heart failure may require ***continuous close observation to detect signs of decompensation, abnormal fluid balance, or adverse effects resulting from prescribed medication(s) that serve as indicators for adjusting therapeutic measures***. . . . Patients who, in addition to their physical problems, exhibit acute ***psychological symptoms such as depression, anxiety, or agitation***, may also require skilled observation and assessment by

> technical or professional personnel to ensure their safety or the safety of others, that is, ***to observe for indications of suicidal or hostile behavior***. . . .

347. As explained thoroughly above, Joe's Locked-In Syndrome and various other serious health problems absolutely require "a technical or professional person . . . to identify and evaluate" Joe's need for modification of, or additional, treatment, "to detect . . . signs . . . or adverse effects . . . that serve as indicators for adjusting therapeutic measures."

348. Meanwhile, Joe's uncertain mental condition, including his "depression, anxiety, or agitation," demands skilled observation to recognize indications of whether, in Joe's case, he is "working with" or "working against" those who are trying to help him.

349. In addition, Medicare regulation, 42 C.F.R. 409.33, provides a ***non-exhaustive*** list of "Services that qualify as skilled nursing services," including the following:

> (1) ***Intravenous*** or intramuscular injections and intravenous feeding.
>
> (2) ***Enteral feeding that comprises at least 26 per cent of daily calorie requirements*** and provides at least 501 milliliters of fluid per day.
>
> (3) Nasopharyngeal and ***tracheostomy aspiration***;
>
> (4) ***Insertion and sterile irrigation and replacement of suprapubic catheters***;
>
> (5) ***Application of dressings involving prescription medications and aseptic techniques***;
>
> (6) ***Treatment of extensive decubitus ulcers*** or other widespread skin disorder;
> . . . .
> (9) ***Rehabilitation*** nursing procedures . . . .

350. Also, Medicare regulation, 42 C.F.R. 409.33, provides a list of "Examples of skilled nursing and rehabilitation services," including the following:

> (2) ***Therapeutic exercises*** or activities: Therapeutic exercises or activities which, because of the type of exercises employed or ***the condition of the patient***, must be performed by or under the supervision of a qualified physical therapist or occupational therapist to ensure the safety of the patient and the effectiveness of the treatment;
> . . . .

> (4) ***Range of motion exercises***: Range of motion exercises which are part of the active treatment of a specific disease state which has resulted in a loss of, or restriction of, mobility . . . .

351. As explained thoroughly herein, on a daily or regular basis Joe requires and receives, *inter alia*, ***these*** skilled nursing services, including receiving all of his daily calorie requirements by enteral feeding via a PEG tube; receiving total care, and suctioning, of his tracheostomy; the insertion, irrigation, and replacement of his supra-pubic catheter; the application of dressings involving medications and aseptic techniques; the treatment of his pressure ulcers; rehabilitative nursing procedures including range of motion and splinting therapies; and intravenous injections when necessary to treat infection – all of which are further complicated by Joe's overall condition, his Locked-In Syndrome, and other health problems.

352. Notably, in TRICARE's March 16, 2010 reconsideration determination, TRICARE claimed that it had only, and erroneously, approved prior coverage periods for Joe's care at Crestmont "based on [Joe's] feeding tube alone, but this on its own is not criteria for skilled level need."

353. But, according to the Medicare guidelines for skilled nursing coverage, there is no question that "[e]nteral feeding that comprises at least 26 per cent of daily calorie requirements and provides at least 501 milliliters of fluid per day" qualifies as a skilled nursing service.

354. TRICARE's decision denying skilled nursing facility coverage to Joe Flores utterly ignored the very standards, provided under Medicare, that Congress commanded shall dictate skilled nursing coverage decisions under TRICARE.

355. TRICARE ignored the fact that Joe Flores's care at Crestmont constitutes skilled care based on the "overall management and evaluation of care plan" that is required to adequately care for Joe, given his Locked-In Syndrome and other health problems.

356. TRICARE ignored the fact that Joe Flores's care at Crestmont constitutes skilled

care based on the "observation and assessment of the patient's changing condition" that is required to adequately care for Joe, given his Locked-In Syndrome and other health problems.

357. TRICARE ignored the fact that Joe Flores's care at Crestmont constitutes skilled care based on numerous individual services that Joe requires at on a daily/regular basis, given his Locked-In Syndrome and other health problems.

358. If TRICARE had fully analyzed the care Joe receives at Crestmont, especially given his "total condition" (Medicare Benefit Policy Manual, Ch. 8), and applied all of the proper standards for SNF coverage provided by Medicare for TRICARE coverage decisions – as TRICARE should have – TRICARE would have, and should have, reached a different decision.

D. THE CARE JOE FLORES RECEIVES AT CRESTMONT IS NOT, UNDER FEDERAL LAW, EXCLUDED FROM COVERAGE AS "CUSTODIAL CARE"

359. Instead of analyzing Joe Flores's total condition, the myriad individual skilled services Joe requires on a daily basis, and the detailed Medicare guidelines under which Congress requires Joe's care be analyzed, TRICARE simply concluded – without analysis – that Joe's care was excluded as "custodial care."

360. "Custodial care" is excluded from TRICARE coverage. 10 U.S.C. 1077(b)(1); 32 C.F.R. 199.4(g)(7). The military health benefits statute defines "custodial care" as "treatment or services, regardless of who recommends such treatment or services or where such treatment or services are provided, that –

> (A) can be rendered safely and reasonably by a person who is not medically skilled; or
>
> (B) is or are designed mainly to help the patient with the activities of daily living."

10 U.S.C. 1072(8); 32 C.F.R. 199.2(b).

361. The current definition of "custodial care" was added to the military health benefits

statute (10 U.S.C. ch. 55) by Congress by way of the National Defense Authorization Act of Fiscal Year 2002, Public Law 107-107 (2001), whereby Congress also added the new statutory section providing the "skilled nursing facility benefit," discussed above.

362. In its Final Rule (61368 Federal Register, vol. 70, no. 204 (Oct. 24, 2005)) after this legislative change, the Department of Defense unambiguously acknowledged that the congressional intent and purpose of the new definition of "custodial care" was to ***narrow*** the exception, and to ***increase*** the availability of coverage, making it on par with Medicare.

363. As stated by the Department of Defense in its Final Rule:

> ***[T]he new definition for custodial care <u>narrows</u> the exclusion, resulting in increasing coverage of medically necessary custodial care. This is also consistent with the Congressional effort largely to standardize TRICARE and Medicare sub acute care coverage***[.]

364. As further stated by the Department of Defense in its Final Rule:

> ***[T]he <u>narrowing</u> of the regulatory definition of custodial care***, which previously was statutorily excluded but not defined, by the adoption of the new statutory definition of "custodial care" that ***has the effect of eliminating current program restrictions*** on paying for certain medically necessary custodial care.

365. Also, as stated by the Department of Defense in its Final Rule:

> ***The <u>narrowing</u> of the definition of custodial care <u>expanded</u> the benefits available*** to certain TRICARE beneficiaries. This satisfied ***the Congressional goal*** of revising TRICARE's definition of custodial care and expanding TRICARE's benefits.

366. Clearly, the Department of Defense itself fully recognized that Congress intended the "custodial care" exclusion to be applied in an extremely narrow fashion and construed to expand, not decrease, the health benefits (including skilled nursing facility coverage) to which military beneficiaries are entitled, under Medicare standards.

367. Regarding the first component of the "custodial care" definition, Joe Flores's care at Crestmont ***cannot*** be "rendered safely and reasonably" by an unskilled person, without at least

the supervision of a skilled medical professional, as described thoroughly herein.

368. Regarding the second component of the "custodial care" definition, Joe Flores's care is not "designed ***mainly***" to help him with the "activities of daily living."

369. TRICARE regulations, 32 C.F.R. 199.2(b) – and not the military health benefits statute, which does not define the term – offer this definition of "activities of daily living":

> Care that consists of providing food (including special diets); clothing, and shelter; personal hygiene services; observation and general monitoring; bowel training or management (unless abnormalities in bowel function are of a severity to result in a need for medical or surgical intervention in the absence of skilled services); safety precautions; general preventive procedures (such as turning to prevent bedsores); passive exercise; companionship; recreation; transportation; and such other elements of personal care that reasonably can be performed by an untrained adult with minimal instruction or supervision.

370. As stated in TRICARE's regulation, these are "elements of personal care."

371. Joe Flores's care at Crestmont is not "mainly" designed to help with "elements of personal care." As described thoroughly herein, given Joe Flores's total condition, his Locked-In Syndrome, and his various other serious health problems, the extremely nuanced, around-the-clock medical care, assessment, supervision, and rapid intervention that is provided to Joe Flores at Crestmont is "designed mainly" to keep Joe alive. According to his own long-time treating physician, without the care he receives at Crestmont, he would deteriorate very quickly.

372. Meanwhile, as stated in the Medicare regulations under which SNF (skilled nursing) coverage decisions by TRICARE should be decided, "[c]ustodial care is any care that does not meet the requirements for coverage as SNF care as set forth in [the Medicare regulations governing skilled nursing care]." 42 C.F.R. 411.15.

373. As described thoroughly herein, on various grounds, Joe Flores's care at Crestmont "meets the requirements for coverage as SNF care" under Medicare.

374. As stated in the Medicare Benefit Policy Manual, Chapter 16, "[c]ustodial care

essentially is personal care that does ***not*** require the continuing attention of trained medical or paramedical personnel."

375. Joe Flores's care at Crestmont is primarily the opposite – medical care that ***requires*** "the continuing attention" of skilled nursing personnel.

376. Before the "custodial care" exclusion was amended – and narrowed – in 2001, courts had examined agency interpretation of the exclusion and found that the exception was being read too broadly, and not in line with congressional intent.

377. For example, the Department of Defense wrongfully denied coverage – based on an overly broad reading of the "custodial care" exclusion – to a severely disabled military beneficiary like Joe Flores. *Barnett v. Weinberger*, 818 F.2d 953 (D.C. Cir. 1987).

378. The *Barnett* court recognized that "[e]ven where immediate, constant care is not required, the unstable condition of [a] patient may thus necessitate skilled nursing supervision." *Barnett*, *supra* at 970. "It was never intended by Congress that the condition of the insured, treatment that might at any time be necessary, and the pain and discomfort attending inadequate or unprofessional care or lack of care not be considered together with treatment actually provided in determining whether extended care services are justified." *Id.*, quoting *Sowell v. Richardson*, 319 F. Supp. 689, 692 (D.S.C. 1970).

379. When determining whether health care is "custodial care," "[t]he critical factor is not the division or percentage of the labor daily received by the patient, but the essential nature of the patient's call for supervision and ministration, even if considerably less frequent, from medical professionals." *Barnett*, *supra* at 969. If this were not the case, "the more debilitating the ailment affecting a claimant, the more likely the care will be termed 'custodial,' since even the simplest bodily tasks will require assistance and supervision." *Id.*

380. What otherwise might be considered "custodial care" standing alone may be

considered, under the military health benefits statute, medical care "in light of the statute's benevolent congressional purpose" and considering "the needs and underlying condition of the claimant insured as a whole." *Barnett*, *supra* at 670.

381. The fact that Joe Flores needs assistance with some activities of daily living does not in any way render the skilled care that he requires any less significant. Indeed, most medical problems that require skilled care also involve some degree of supplemental, non-medical care.

382. The important factor in determining that Joe Flores's care at Crestmont is not "custodial care" is Joe's needs and underlying condition "as a whole," including his Locked-In Syndrome, other health problems, and the fact that, on a daily or regular basis Joe requires and receives, *inter alia*, skilled nursing services, including receiving all of his daily calorie requirements by enteral feeding via a PEG tube; receiving total care, and suctioning, of his tracheostomy; the insertion, irrigation, and replacement of his supra-pubic catheter; the application of dressings involving medications and aseptic techniques; the treatment of his pressure ulcers; rehabilitative nursing procedures including range of motion and splinting therapies; and intravenous injections when necessary to treat infection.

383. Meanwhile, because of his condition as a whole, Joe is extraordinarily susceptible to various illnesses and infections, and he has developed life-threatening infections in the past.

384. The only reason why Joe has not suffered more serious problems over the last 6 years is precisely ***because*** he has received skilled nursing care at Crestmont.

385. Because of the around-the-clock skilled nursing care, assessment, supervision, and rapid intervention that Joe receives at Crestmont, Joe has been able to survive despite his precarious condition.

386. The fact that Joe Flores' exceedingly debilitating condition requires assistance with some activities of daily living – cleaning Joe and helping with re-positioning him – in

addition to around-the-clock skilled care, assessment, supervision, and rapid intervention, does not render Joe's care at Crestmont "custodial care."

387. Joe's care at Crestmont is not "***mainly***" to help with mundane "activities of daily living." 10 U.S.C. 1072(8); 32 C.F.R. 199.2(b). In the aggregate, the care Joe receives at Crestmont is designed "mainly" to medically prevent Joe from dying.

388. Based upon a proper interpretation of the "custodial care" exclusion, and a proper interpretation of the skilled nursing facility benefit, Joe's care is not excluded as "custodial care."

389. As held in the *Barnett* case, the Department of Defense's "broad-gauged reading of the statutory [custodial care] exclusion is antithetical to the general statutory purpose, for the prime objective of the Dependents Medical Care Act was enhancement, not reduction, of the benefits to be accorded to military personnel and their dependents." *Barnett v. Weinberger*, 818 F.2d 953, 963 (1987).

390. Congress decided that military personnel, active duty and retired, deserve a premium level of medical care. A stingy interpretation of TRICARE coverage to exclude life-saving medical care to Joe Flores, under a statute pursuant to which Congress commands the Department of Defense to provide premium health care for persons like Joe who served and sacrificed for this country, is contrary to the core purposes of the military health benefits statute.

391. Where an administrative interpretation is not consonant with congressional intent, that interpretation is not owed judicial deference. It is well established that "[i]n order for an agency interpretation to be granted deference, it must be consistent with the congressional purpose." *CBS, Inc. v. Democratic Nat'l Comm.*, 415 U.S. 94, 122 (1973).

392. Here, the Department of Defense's interpretation of the "custodial care" exception, which eliminates coverage for medically necessary treatment, is not in line with congressional intent, and it should not be given judicial deference.

VIII. DEFENDANTS' WRONGFUL DENIAL OF SKILLED NURSING FACILITY CARE TO JOE FLORES IS CAUSING HIM IRREPARABLE AND CATASTROPHIC HARM

393. By refusing to cover the skilled nursing care which Joe requires, the Department of Defense is imposing a death sentence on Joe Flores.

394. Defendants' unlawful, arbitrary and capricious actions have left Joe Flores to his own, extremely limited devices to somehow obtain the skilled nursing facility care that he desperately needs.

395. Joe Flores is being irreparably harmed by Defendants' wrongful denial of coverage.

396. Since Defendants' denial of coverage for Joe's skilled nursing care, Joe has been paying out-of-pocket for his care at Crestmont – which totals approximately $7,000 per month – from his own, extremely limited personal funds.

397. Very soon, Joe will deplete his savings, will be unable to pay for his care, and will face immediate and irreparable harm without such care, including, potentially, death.

398. Without continued skilled nursing care, Joe's chances for survival are slim.

IX. CLASS ACTION ALLEGATIONS

399. Plaintiffs bring this case as a class action against Defendants pursuant to Rule 23 of the Federal Rule of Civil Procedure, individually and on behalf of a class consisting of all TRICARE beneficiaries diagnosed with Locked-In Syndrome, as comatose, or in a vegetative state who, on or after May 13, 2005, were or are denied coverage for skilled nursing facility care, where TRICARE denied or denies coverage for skilled nursing facility care on the basis that such care is custodial care or is otherwise not medically necessary.

400. Plaintiffs are members of the class and will fairly and adequately assert and protect the interests of the class.

401. The interests of Plaintiffs are consistent with, and not antagonistic to, those of the other members of the class.

402. The claims of Plaintiffs are typical of the claims of the class, and the class action method is appropriate for the fair and adequate prosecution of this action.

403. Plaintiffs have retained attorneys who are experienced in class action litigation, and who will provide adequate representation.

404. Members of the class are so numerous that joinder of all members of the class is impracticable.

405. Upon information and belief, there are thousands of members of the class whose identities can be ascertained from the records and files of Defendants and from other sources.

406. Research shows that there are approximately 50,000 persons with Locked-In Syndrome, among the approximately 300,000,000 persons in the United States.

407. Meanwhile, there are approximately 9.6 million TRICARE beneficiaries. Applying the percentage of persons in the United States who have Locked-In Syndrome to the total number of TRICARE beneficiaries suggests that there are at least 1,600 TRICARE beneficiaries with Locked-In Syndrome.

408. In addition, upon information and belief, there are many more thousands of TRICARE beneficiaries who are comatose or in a vegetative state.

409. Upon information and belief, Defendants are regularly denying skilled nursing facility benefits to TRICARE beneficiaries who have Locked-In Syndrome, are comatose, or are in a vegetative state, on the basis that such care is custodial care or is otherwise not medically necessary.

410. Common questions of law and fact as to Defendants' violations of the military health benefits statute (10 U.S.C. ch. 55) as well as the APA, which have caused and will

continue to cause harm to the class, predominate over any question affecting only individual members of the class.

411. The prosecution of separate actions by individual members of the class would create a risk of, among other things, the following:

a. Inconsistent or varying adjudications with respect to individual members of the class; and

b. Adjudication with respect to individual members of the class which would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication or substantially impair or impede their ability to protect their interests.

412. Individual litigation of claims which might be commenced by all class members would produce a multiplicity of cases such that the judicial system having jurisdiction of the claims would remain congested for years.

413. Class treatment, by contrast, provides manageable judicial treatment calculated to bring a rapid conclusion to all litigation of all claims arising out of conduct of Defendants related to the wrongful denial of coverage for skilled nursing facility care for TRICARE beneficiaries with Locked-In Syndrome, or who are comatose or in a vegetative state.

414. The certification of a class would allow litigation of claims that, in view of the expense of litigation, may be insufficient in amount to support separate claims.

415. As individuals, Plaintiffs and the class members they represent have few or no surplus resources to prosecute their claims for relief unless they aggregate their resources with similarly situated TRICARE beneficiaries, and take advantage of the class action rule that permits a prevailing party to recover attorneys' fees and costs from the Defendants.

416. Most of the Plaintiff TRICARE beneficiaries and families have been stripped of material wealth by choosing service to the nation instead of the pursuit of personal wealth in the private economy and by having to exhaust their modest pay on the basic necessities of life and

health care, because the Department of Defense refuses to pay for the health care to which they are entitled by law.

X. DEFENDANTS' VIOLATIONS OF THE ADMINISTRATIVE PROCEDURE ACT

COUNT I - VIOLATIONS OF 5 U.S.C. 706

417. Plaintiffs reallege all preceding allegations.

418. The TRICARE program covers medically or psychologically necessary health care, including skilled nursing facility care.

419. Defendants have denied coverage for health care to which Joe Flores and the class are entitled under 10 U.S.C. ch. 55 as TRICARE program beneficiaries.

420. Defendants' denial of coverage is contrary to law and regulation, and is also arbitrary and capricious.

421. Joe Flores and the class of TRICARE program beneficiaries have been negatively affected by Defendants' unlawful determinations.

422. Pursuant to 5 U.S.C. 706, the Court should set aside Defendants' determinations and order Defendants to cover and pay for all medically or psychologically necessary health care, including skilled nursing facility care, for Joe Flores and the class of TRICARE program beneficiaries from this day forward.

423. Pursuant to 5 U.S.C. 706, the Court should set aside Defendants' determinations and order Defendants to pay for all health care to which Joe Flores and the class of TRICARE program beneficiaries were entitled in the past.

XI. CONCLUSION AND REQUEST FOR RELIEF

424. Defendants' actions have deprived Joe Flores and the class of TRICARE beneficiaries of health care benefits to which they are entitled by law.

425. Defendants' actions are causing irreparable harm to Joe Flores and the class.

426. Plaintiffs and the class seek injunctive relief, declaratory relief, reimbursement, interest, and future TRICARE coverage for the health care benefits that the Department of Defense has wrongfully withheld.

WHEREFORE, Plaintiffs request that this Court:

A. Declare that the care Joe Flores and the class members received and receive at a skilled nursing facility is medically necessary, skilled nursing health care to which they are entitled pursuant to 10 U.S.C. ch. 55 and Defendants' denial of TRICARE benefits is, therefore, wrongful, void, and set aside;

B. Declare that the care Joe Flores and the class received and receive at a skilled nursing facility is not "custodial care" for purposes of 10 U.S.C. ch. 55 and Defendants' denial of TRICARE benefits is, therefore, wrongful, void, and set aside;

C. Enjoin Defendants to provide TRICARE coverage for Joe Flores's and the class members' past, present, and future care provided at a skilled nursing facility, as required by 10 U.S.C. ch. 55;

D. Award Joe Flores and the class members the maximum allowable TRICARE benefit for skilled nursing facility care, and reimbursement for all costs incurred for skilled nursing facility care covered under TRICARE;

E. Grant a monetary award to the Plaintiffs for the costs and inconvenience associated with bringing this action on behalf of the class of TRICARE beneficiaries;

F. Award attorneys' fees and costs associated with prosecuting this action;

G. Award all necessary and appropriate equitable, declaratory, and injunctive relief to which Plaintiffs and the class members are entitled;

H. Award all other such relief as the Court may deem appropriate and in the interest of justice.

Respectfully submitted,

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